Steps to Qualify or Validate Data after a Failed Critical Criteria Checks

In order to address issues related to the recent OIG Management Alert[1] associated with findings of failed 1-point quality control (QC) checks and data invalidation, EPA is providing some additional guidance on the process to validate or invalidate routine data based on an exceedance of important checks that have been identified as "critical criteria" in the QA Handbook[2]. These critical criteria checks[3] are part of a validation template that were developed for all criteria pollutants around 2006 by EPA and the monitoring organizations. Monitoring organizations, in their organizations specific quality assurance project plans, may identify additional checks that they deem critical. The definition of the critical criteria can be found in Appendix D of the QA Handbook but the following quote is the driver behind this guidance:

> "Observations that do not meet each and every criterion on the Critical Criteria should be invalidated unless there are compelling reasons and justification for not doing so."

Compelling evidence (reason) is data, such as (but not limited to) an independent audit point(s), a multi-point verification, and/or a prior zero/span check that establishes whether the analyzer was in fact operating within the percent difference critical criteria acceptance limits and whether the 1-point QC check itself is considered valid or invalid. This evidence is either available from routine tests within the timeframe of the last acceptable valid QC check or from an independent test/check that establishes that the system that produced the 1-QC was invalid once the failure is discovered. Because these are critical criteria, timely action (ie, no later than the next day) on the part of the monitoring organization to determine why such a "critical" failure occurred should be the normal course of action.

We define valid and invalid QC checks as follows:

- A valid QC check is one that is conducted using certified, properly functioning equipment, conducted in a manner that adheres to appropriate procedures (SOPs), and the test concentration is accepted as accurate.
- An invalid QC check is check in which there were technical issues with the generation of its test concentration and the test concentration is not accepted as accurate.

A valid QC check which exceeds acceptance criteria (i.e., "fails") will result in at least some routine data invalidation, but sometimes there is "compelling evidence" available regarding corrective actions and/or additional analyzer checks that may not be readily viewable in the AQS dataset that helps bracket the data set to be invalidated. ~~A valid QC check is one that is conducted using certified, properly functioning equipment, conducted in a manner that adheres to appropriate procedures (SOPs).~~ ~~However, there may be cases (as described in scenarios #2 and #3 below) where additional information demonstrates~~

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[1] Report: Certain State, Local and Tribal Data Processing Practices Could Impact Suitability of Data for 8-Hour Ozone Air Quality Determinations [HYPERLINK "https://www.epa.gov/office-inspector-general/report-certain-state-local-and-tribal-data-processing-practices-could"]

[2] Quality Assurance Handbook for Air Pollution Measurement Systems Volume II Ambient Air Quality Monitoring Program [HYPERLINK "https://www3.epa.gov/ttn/amtic/qalist.html"]

[3] Although the guidance focuses on 1-point QC checks since it is the only check currently reported to AQS. There are other critical criteria that fall within the QA Handbook guidance

~~that a QC check that exceeded the acceptance limits was for some reason, invalid.~~ We need to use, evaluate and report both valid and invalid QC checks in a consistent manner.

The following ~~two~~three scenarios may exist for a monitor when a 1-point QC check has exceeded the established acceptance criteria. A flowchart follows that describes these ~~two~~three scenarios:

Scenario 1

~~1.~~ A 1-point QC check exceeds the established acceptance criteria. Upon investigation, the operator determines that the 1-point QC check provided a valid concentration and that the analyzer needs adjustment/calibration. This confirmation provides evidence that the 1-Point QC check was in fact a valid check and, ~~consequentlyresultantly~~, routine data should be invalidated.

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Flagging Process for Scenario 1

1. The 1-Point QC check is reported to AQS, and the null code "~~EC~~AS" (exceeds critical criteria~~poor QA Results~~) replaces the routine data either back to the last acceptable 1-point QC check or where additional compelling evidence exits (see #2). "EC" is not the only null code that can be selected. Other null codes more definitive of the monitors failure can also be selected (e.g., "AN" for machine malfunction) in lieu of the "EC" null code. Where a monitoring organization responds to a QC check exceedance with an adjustment/recalibration, it should be followed by another reported QC check at the same concentration as the previous exceedance check in order for the routine data between this valid passing check and the next scheduled check to be considered valid.
2. ~~Ief~~ there ~~where there~~ is compelling evidence (i.e., ~~an~~ acceptable more frequent zeroes and spans which show a clear pattern change, or other verification) to accept some of the data between the exceedance and the last valid 1-point QC check, ~~In this case,~~ the routine data that was valid would be reported and flagged "1V" (data was reviewed and validated). The ~~while the data that was not supported by compelling evidence would be flagged with the null code "AS"~~ompelling evidence needs to be documented (described below).
3. EPA Regions, during the annual certification/concurrence process, will be able to evaluate the information and flags used in this process. As mentioned below, with the development of a quarterly AQS report specifically related to these critical "p-checks" (and/ or utilizing existing AQS reports), EPA will be reviewing and evaluating these checks no less than quarterly.

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NOTE: If routine data is invalidated using null codes, the valid QC check, although reported to AQS, will not be used in aggregate statistics of precision and bias since the check is not representing the precision and bias of the routine data for that time period.

NOTE: If no additional verification checks or other investigative measure to find compelling evidence is performed on the analyzer or the QC system following the QC exceedance, then the 1-point QC check will be considered valid and reported to AQS. EPA will consider the routine data suspect and the data should be replaced with the "~~EC~~AS" null code back to the last passing check and forward to the next passing check. Quarterly evaluation reports under development by EPA will highlight this data. If routine data is invalidated, the QC

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concentration, although reported to AQS, will not be used in aggregate precision and bias calculations since the routine data representing the exceedance was invalidated.

Scenario 2 and 3

2. A 1-point QC check exceeds the established acceptance criteria and **there is compelling evidence** to consider the analyzer's data valid (and therefore consider the QC check invalid). For example, after an acceptance criteria exceedance, failure the monitoring organization reviewed the data, went out to the site and conducted an "as is" (no adjustment to analyzer) QC check, performance evaluation, or multi-point verification at a concentration around the original QC check. These additional checks (not limited to the examples described above) demonstrate that the analyzer is operating within the 1-point QC acceptance limits and, therefore, supports the validity of the routine data. This compelling evidence also suggests that corrective action is needed to the QC system that generated the invalid 1-point QC check. It is suggested that corrective action be taken on the QC system immediately in order to determine the definitive cause of the invalid check, which serves as further evidence to support the validity of the routine data. A second acceptable 1-point QC check should be run so that routine data validity is established from the acceptable check to the next scheduled 1-point QC check. It is also not expected that a number of 14-day QC checks would exceed the acceptance criteria before corrective action is taken to discover the there was a problem with the QC system and that the QC checks are invalid.

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3. Similar to scenario #2 where there is compelling evidence but a 1-point QC check was not run immediately after verifying that the analyzer is operating within acceptance limits, but was run within a few business days.

Flagging Process for Scenarios 2 and 3

The following process is for gaseous pollutant data that fail (exceed acceptance criteria) to meet of 1-point QC checks (or Zero/Span) but monitoring organizations **have compelling evidence to consider the routine data valid** (scenarios #2 and 3). In other cases, where a monitoring organization responds to a failing QC check with an adjustment/ recalibration, followed by a verification (ideally, followed by another QC check at the same concentration), the data after the multipoint calibration/ verification until the next passing p-check may be considered valid.

1. The invalid, failed 1-point QC check is not reported to AQS since the QC check is not considered valid. Replace the QC check concentration with a EPA will create a flag field in the QA Transaction and will create an ""IC" null code that can replace the 1-point QC concentration of the audit value. Thes code flag will create a "placeholder" in AQS that will allow to one to identify that a QC check occurred within the required 14-day timeframe for data completeness purposes.
2. Document the evidence related to the invalid QC check. See compelling evidence described below.
2. Routine data within the time frame between the last acceptable check and the next passing check should be flagged with a "1V" signifying the data was reviewed and there is a compelling reason to consider some or all of the data from the last passing QC check valid.

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~~3. During the annual certification process, monitoring organizations will provide compelling evidence for the "1V" flags. The AMP600 Report will be modified to include ways for the monitoring organizations to provide the compelling evidence. As an option, monitoring organizations can provide free form comments in AQS. This comment can be entered via the web application on the maintain raw data form. EPA will work with monitoring organizations and provide additional guidance on this part of the process.~~

3. EPA Regions, during the annual certification/concurrence process, will ~~be able to evaluate the information and flags used in this process~~concur with the data flagged "1V". As mentioned below, with the development of a quarterly AQS report specifically related to these critical "p-checks" (and/ or utilizing existing AQS reports), EPA will be reviewing and evaluating these checks no less than quarterly.

~~4.~~

Compelling Evidence Documentation

Data flagged "1V" after a valid QC check exceedance or a null coded QC check ("IC") should be documented in AQS. Two methods are available for this documentation:

1. **Free form comments in AQS.** This comment can be entered via the web application on the maintain raw data form. EPA is not expecting a complete description of the issue and resolution. Monitoring organization utilize instrument logbooks and site logbooks that should provide the details of the flags used in this guidance. Free form notes can be a simple as "Operator Error: mm/dd/yyyy" which can refer to a logbook entry date that could then be discussed with the EPA Regions during data certification and reviewed during the next technical systems audit. This is the preferred approach.
2. **Part of AMP600 certification and concurrence process.** The AMP600 will be revised to identify issues related to the QC exceedances and whether they have been handled as described in scenarios 1 and 2. If not, the data will be flagged and require some compelling information. Regions can then concur with the compelling evidence. Similar to #1 above, this information can be a short description and refer to a log book entry.

Next Steps

Any routine data represented by failed 1-point QC checks that are not properly flagged in AQS will be identified in EPA quarterly evaluation reports (currently in design phase). Attachment 1 is an initial draft of what this quarterly report may look like. EPA Regions will work with monitoring organizations on this data until a resolution of the validity of this data is reached prior to annual certification/concurrence. Unresolved data issues represented by failed 1-point QC checks may not be considered for regulatory use until completion of the annual certification/concurrence process. ~~of steps 3-4.~~

In addition, 1-point QC checks will be evaluated for completeness in the quarterly reports to ensure a check is performed and reported (via a concentration or a flag) every 14 days. It is strongly suggested that these checks be automated and ~~to be~~ performed more frequently than every 14 days to minimize loss of data due to invalidation. EPA Regions found monitoring organizations running checks more frequently but not reporting them to AQS. We suggest all valid QC checks be reported since it may also serve to minimize data invalidation.

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EPA is in the review/development stages of this process. We will be working with the National Air Data Group to develop the flagging portion which we expect to be available ~~can occur~~ in CY-2017. The revision of the AMP600 will not implemented until May 2019 certification so will be in effect for 2018 data.

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~~fairly quickly with the certification/concurrence part of the process to be ready before May 2018 annual certification and concurrence.~~

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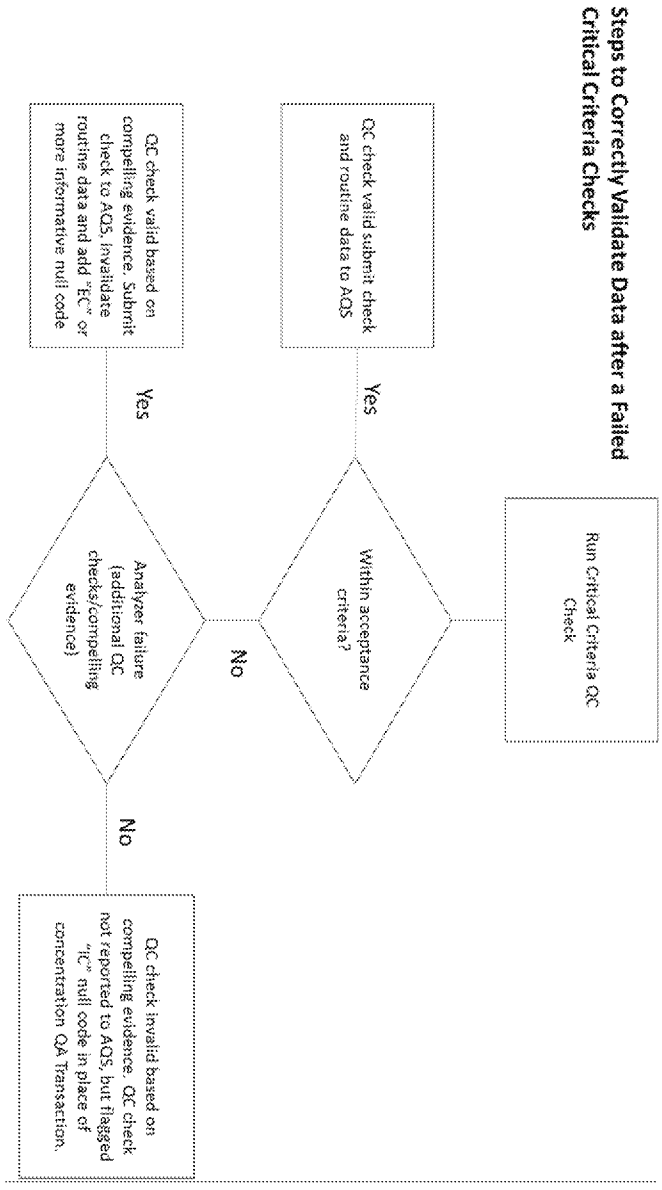


Attachment 1

Development of Automated Quarterly Reports

DRAFT

Goal:

Provide an automated report that would allow OAQPS, Regions and monitoring organizations to determine where there may be data quality issues in AQS that need to be reviewed evaluated and potentially corrected on a quarterly basis.

Program Attributes:

The program will be developed in stages with the first stage devoted to those required QC checks considered critical in the validation template of the QA Handbook and reported to AQS. Acceptance criteria will be based on values listed in the 2017 Validation Templates.

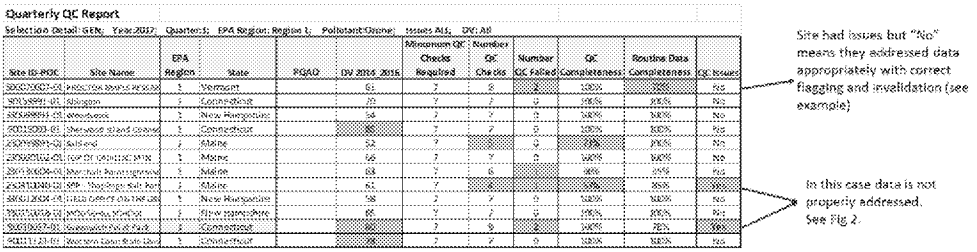
Selection Criteria:

Data can be selected by a number of ways:

- Detail- Select "GEN" for a general table (Fig.1) or "DET" for a general table (Fig.1) and site by site (Fig. 2) report
- Year/quarter- Can select a year, or a year and quarter
- Geographic area
    - EPA Region- select "ALL" for all EPA Regions or by individual Region
    - State- Can select state within an EPA Regions or leave blank
    - PQAO- Can select PQAO within a state or leave blank
- Pollutant- either "ALL" for all criteria pollutants or select by parameter code
- Issues- Can either select "ALL" for all sites within the selection criteria or "ISS" to select those sites where a failure has occurred and the data has not been appropriately flagged or null coded
- DV- Can either select "ALL" for all sites or "DV" to report for those sites at 80% and greater of the design value

Output:

Figures 1 and 2 provide an idea of the reports generated based on the selection criteria. These figures are for the ozone 1-point QC criteria.



Quarterly QC Report

Selection Detail: GEN; Year:2017; Quarter:1; EPA Region: Region 1; Pollutant/Gaseous; Issues: All; DV: All

Site ID-POC	Site Name	EPA Region	State	PQAO	DV 2014- 2016	Minimum QC Checks Required	Number QC Checks	Number QC Failed	QC Completeness	Routine Data Completeness	QC Issues
500070007-01	[illegible]	1	Vermont		61	7	9	0	100%	79%	No
501190991-01	[illegible]	1	Connecticut		70	7	7	0	100%	100%	No
490038991-01	[illegible]	1	New Hampshire		58	7	7	0	100%	100%	No
500150003-01	Sherwood Island [illegible]	1	Connecticut		80	7	7	0	100%	100%	No
230019991-01	[illegible]	1	Maine		52	7	9	0	78%	100%	No
230090102-01	[illegible]	1	Maine		66	7	7	0	100%	100%	No
230130004-01	[illegible]	1	Maine		68	7	6	1	86%	75%	No
230110040-01	[illegible]	1	Maine		61	7	8	1	88%	86%	No
490012004-01	[illegible]	1	New Hampshire		58	7	7	0	100%	100%	No
490150003-01	[illegible]	1	New Hampshire		85	7	7	0	100%	100%	No
500190027-01	[illegible]	1	Connecticut		80	7	9	1	100%	78%	Yes
500110043-01	[illegible]	1	Connecticut		79	7	7	0	100%	100%	No

Site had issues but "No" means they addressed data appropriately with correct flagging and invalidation (see example)

In this case data is not properly addressed. See Fig 2.

Figure 1. Example of a Quarterly Report for 1-point QC Check (example only information fictitious)

Report Details (Fig 1)

The report will highlight a few areas:

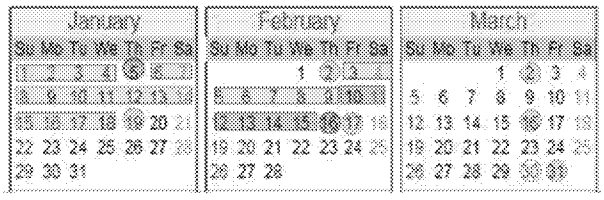
- Design Value Sites- Although you can sort and look at only sites from 80% and greater of the design value if you select "ALL" sites in the DV selection, any sites in a general report that fail within the criteria will also be highlighted (DV = All).
- QC Number Failed - Any site with a failed QC (whether the QC value was valid or not) will be highlighted.
- QC Completeness- Any site with QC completeness <75% will be highlighted.
- Routine Data Completeness- Any site with routine data completeness <75% will be highlighted
- Issues – any site that did not provide correct flagging of their data or did not invalidate their data (based on appropriate null codes and data flags) will be highlighted (see Fig. 2)

Site Report (Fig 2)

The site report will provide similar detail to the Region 3 504 Report in both a graphical (left) and a table style. It provides some of the information in the general report but then provides more detail. Color coding helps to provide information about the data reported to AQS and whether there is compelling evidence to keep routine data that have failed a valid QC check. See the scenarios for the example site in Figure 2.

2017 Quarterly 1-Point QC Report-Quarter 1
(Example only Information Fictitious)

PQAO Code- 0251 PQAO Name- Connecticut Pollutant- Ozone
Site ID 09-001-0017 Site Name- Greenwich Point Park Design Value Site – Y QC Issue -Y



Passing QC Check
Invalid QC Check (Flagged QC Value)
QC Check Exceedance (valid)

1-Point QC Checks Values

Date	% diff	Dates Effected
1/5/17	8.95%	12/18/16-1/18/17
1/19/17	3.5%	NA
2/2/17	6.2%	NA
2/16/17	7.8%	2/10/17-2/16/17
2/17/17	2.5%	NA
3/2/17	2.5%	NA
3/16/17	3.4%	NA
3/30/17	8.2%	NV
3/31/17	2.6%	NA

1-Point QC Completeness=100%
(due to extra QC samples on 2/17 & 3/31)

Invalid routine data **NOT** flagged "EC"
Valid routine data flagged"1V"
Invalid routine data flagged "EC"

Figure 2. Quarterly Site Report

Scenarios

1/5/2017- QC check exceedance (valid QC check) and monitoring organization properly invalidated data and utilized "EC" null code

2/16/2017 – QC check exceedance (valid QC check) and monitoring organization found compelling evidence to keep data from 2/3 to 2/9 and reported a "1V" qualifier on the routine data. However, they left the remaining concentration data in AQS without a flag or null code. They recalibrated the analyzer and ran another QC check the next day which passed.

3/30/2017- A QC check failed but the monitoring organization went out and did an independent audit and found the analyzer was within acceptance limits and found a leak in the calibration system. Therefore, the QC Check was invalid and reported a "IC" null code to the QA transaction in lieu of a measurement result. After fixing QC system they ran another 1-point QC check that passed.

Steps to Correctly Validate Data after a Failed Critical Criteria Checks